**Recommendations of the SEC (Cardiovascular) made in its 12th/25 meeting held on 11.09.2025 at CDSCO (HQ), New Delhi:**

| S. No. | File Name & Drug Name, Strength | Firm Name | Recommendations |
|---|---|---|---|
| **GCT Division** | | | |
| 1. | CT/62/25<br>Online Submission (49590)<br><br>LY3502970 | M/s Clinical Trials Eli Lilly and Company India Pvt. Ltd | In light of earlier SEC recommendation dated 12.06.2025. The firm presented data in hypertension patients only to conduct the phase III clinical study protocol no. J2A-MC-GZPL version no. initial dated 24 Jan 2025.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm. |
| 2. | CT/52/25<br>Online Submission (49488)<br><br>Vicadrostat<br>(BI 690517) | M/s IQVIA RDS (India) Private Limited | In light of earlier SEC recommendation dated 05.06.2025. The firm presented following information / data before SEC committee:<br><br>1. PI for CVOT trial should have qualification of DM/DNB Cardiology.<br><br>2. Phase II trial data with Vicadrostat in relation to drug interaction with beta blockers and ARNI which are used for heart failure with reduced EF for phase III clinical study protocol no. 1378-0018 version no. 1.0 dated 14 Jan 2025.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that Hyperkalemia should be strictly monitor during the study. |
| 3. | CT/114/25<br>Online Submission (51287)<br><br>LY3473329 | M/s.Clinical Trials Eli Lilly and Company India Pvt. Ltd | The firm presented phase III clinical study protocol no. J2O-MC-EKBG version no. Initial dated 12.May 2025.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm. |
| 4. | CT/117/25<br>Online Submission (51380)<br><br>Enlicitide Decanoate | M/s MSD Pharmaceuticals Private Limited | The firm didn't turn up for presentation. |

| S. No. | File Name & Drug Name, Strength | Firm Name | Recommendations |
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| **SND Division** | | | |
| 5. | SND/MA/23/000221<br><br>Nifedipine Extended Release film coated tablets USP 90 mg (Additional Strength) | M/s Unique Pharma Ltd. | In light of earlier SEC recommendation dated 09.07.2024, the firm presented BE study report conducted under fasting condition along with justification for BE study in fed condition before the committee.<br><br>The committed noted that Nifedipine Extended Release tablet USP 90mg has been approved in US since year 2002 and in other key countries.<br><br>After detailed deliberation, the Committee accepted the bioequivalence (BE) study results conducted under fasting conditions for the proposed formulation. However, the Committee opined that the firm should conduct BE study under fed condition for Nifedipine Extended Release Tablets USP 90 mg. Further, the firm should submit the relevant clinical data along with the BE study report to CDSCO for further review by the Committee.<br><br>Accordingly, the firm should submit the BE Study Protocol under fed condition along with relevant clinical data to CDSCO for further review. |
| **FDC Division** | | | |
| 6. | FDC/MA/25/000127<br><br>Cilnidipine IP 20 mg + Metoprolol Succinate IP 47.5 mg eq. to Metoprolol Tartrate 50 mg (ER) film coated bilayered tablet | M/s Ajanta Pharma Limited | The firm presented their proposal along with BE study protocol under fasting condition before the committee.<br><br>After detailed deliberation, the committee recommended to modify the inclusion criteria in presented BE study protocol as below:<br>“For female participants the minimum Hb%, cut off value should be more than 12g/dl.”<br><br>Accordingly, the firm should submit revised BE study protocol under fasting condition as well as BE study protocol under Fed condition along with Phase III CT protocol to CDSCO for further review by the committee. |

| S. No. | File Name & Drug Name, Strength | Firm Name | Recommendations |
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| 7. | FDC/MA/25/000185<br><br>Cilnidipine IP 20mg + Metoprolol Succinate IP eq. to Metoprolol Tartrate 50mg (ER) film coated tablet | M/s Unique Pharmaceutical Laboratories | The firm presented their proposal along with BE study protocol under fasting condition before the committee.<br><br>After detailed deliberation, the committee recommended to modify the inclusion criteria in presented BE study protocol as below:<br>"For female participants the minimum Hb%, cut off value should be more than 12g/dl."<br><br>Accordingly, the firm should submit revised BE study protocol under fasting condition as well as BE study protocol under Fed condition along with Phase III CT protocol to CDSCO for further review by the committee. |